UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/644,335	08/20/2003	Johan M. Stoop		7986

23906 7590 04/17/2006

E I DU PONT DE NEMOURS AND COMPANY
LEGAL PATENT RECORDS CENTER
BARLEY MILL PLAZA 25/1128
4417 LANCASTER PIKE
WILMINGTON, DE 19805

EXAMINER	
PAGE, BRENT T	

ART UNIT	PAPER NUMBER
1638	

DATE MAILED: 04/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/644,335	STOOP, JOHAN M.	
	Examiner	Art Unit	
	Brent Page	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 February 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26* is/are pending in the application.

4a) Of the above claim(s) *12,18-22,25 and 26* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11,13-17,23 and 24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *20 August 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *05/03/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant's election without traverse of Group I, claims 1-11, 13-17, 23 and 24 in the reply filed on 02/20/2006 is acknowledged.

Claims 12, 18-22, 25 and 26 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 02/20/2006.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-11, 13-17, 23 and 24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 1-11, 23 and 24 are broadly drawn to a plant comprising at least one recombinant DNA molecule comprising an embryo specific promoter operably linked to at least "a portion" of at least one coding sequence for a plant fructosyltransferase, operably linked to a vacuole targeting sequence, wherein said molecule is sufficient to express a protein capable of producing a fructan with a degree of polymerization of at least three in an embryo of said plant, and grain of said plant.

Claims 13-15 are broadly drawn to a recombinant DNA molecule comprising an embryo specific promoter operably linked to at least a "a portion" of at least one coding sequence for fructosyltransferase, operably linked to a vacuole targeting sequence.

Claims 16-17 are broadly drawn to a method of producing fructan in a plant comprising constructing at least one recombinant DNA molecule comprising an embryo specific promoter operably linked to at least "a portion" of at least one coding sequence for a fructosyltransferase, operably linked to a vacuole targeting sequence.

A sequence containing at least "a portion" of at least one coding sequence for a plant fructosyltransferase encompasses multiple embodiments which would include sequences having as little as two nucleotides identical to a plant fructosyltransferase. These multiple embodiments are thus merely limited to coding sequences that are sufficient to express a protein capable of producing a fructan with a degree of polymerization of at least three. The multitudes of sequences include bacterial, or yeast sequences as well as any plant source. Furthermore, absent a SEQ ID NO, any nucleotide substitutions, deletions or rearrangements are also encompassed by the claims.

In contrast, the specification only provides guidance for Jerusalem artichoke SST (contained within SEQ ID NO:1), Jerusalem artichoke FFT (contained within SEQ ID NO: 2), Guayule SST (SEQ ID NO:10) and Guayule FFT (SEQ ID NO: 13) coding sequences. The specification does not provide guidance for coding sequences from any other plant source, or any other organismal source in which a fructan with a degree of polymerization of 3 is produced in the embryo of a plant.

The function of different 1-FFT genes is unpredictable. Vergauwen et al (Plant Physiology 2003, 133:391-401) in a review of the role of 1-FFT in Inulin production of different species found that very different degrees of polymerization were found among different species of plants, in particular chicory and globe thistle (see page 391 second full paragraph, and page 399, second and third full paragraphs). In addition not all 1-FFT genes have been characterized in all plant species, or for that matter in other species as broadly claimed and therefore undue experimentation would be required to isolate, sequence, and characterize the enzymatic function of all 1-FFT genes of all species. The specification also does not provide any guidance for functional domains of either 1-FFT genes or SST genes, or the amount of conservation in DNA sequence required for activity of the enzymes encoded by the DNA sequences. Without this guidance, undue experimentation would be required to determine all the embodiments of all 1-FFT and SST genes that are "sufficient" to express a protein "capable" of producing fructan having a degree of polymerization of at least three. In a study of the functional domains for fructosyl transferases, Ritsema et al (2004 Plant Molecular Biology 54:853-863) discovered that switching the sucrose binding boxes of FFT, SST, and invertase, along with site directed mutagenesis resulted in different fructosyl transferase activity and function (see page 857 last full paragraph, page 859 last two full paragraphs, for example). Caimi et al (WO 95/13389) disclose that point mutations in the bacterial fructosyltransferase gene, FTF, transformed into tomato plants resulted in viable, apparent full length RNA transcripts, but are not translated into function FTF proteins (see page 43, line 8 through page 44 line 8 for example).

The viability of transgenic plants that accumulate fructan is unpredictable. Turk et al (1997 New Phytology 136:29-38) disclose transgenic tobacco plants transformed with the E. coli levansucrase gene may have deleterious defects in the form of bleached leaves, stunted growth and reduced root growth (see page 36 last paragraph, for example). Caimi et al (WO 95/13389) disclose the lack of viability in shoots of transgenic tobacco plants that were transformed with the bacterial fructosyltransferase gene SacB (see page 68 lines 18-33, for example). Undue experimentation would be required to evaluate all fructosyltransferase coding sequences for their effect on fructan accumulation and plant viability.

Given the claim breadth, unpredictability, and lack of guidance as discussed above, undue experimentation would have been required by one skilled in the art to isolate and evaluate all fructosyl transferase coding sequences, or portions thereof for their sufficiency to express a protein capable of producing fructan having a degree of polymerization of at least three as claimed (see Atlas Powder Co. v. E.I. du Pont de Nemours & Co., 750 F.2d 1569, 1576, 224 USPQ 409, 413 (Fed. Cir. 1984) where a significant number of inoperative embodiments was deemed to indicate an undue amount of experimentation).

Claims 1-11, 13-17, 23 and 24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

Claims 1-11, 23 and 24 are broadly drawn to a plant comprising at least one recombinant DNA molecule comprising an embryo specific promoter operably linked to at least "a portion" of at least one coding sequence for a plant fructosyltransferase, operably linked to a vacuole targeting sequence, wherein said molecule is sufficient to express a protein capable of producing a fructan with a degree of polymerization of at least three in an embryo of said plant, and grain of said plant.

Claims 13-15 are broadly drawn to a recombinant DNA molecule comprising an embryo specific promoter operably linked to at least a "a portion" of at least one coding sequence for fructosyltransferase, operably linked to a vacuole targeting sequence.

Claims 16-17 are broadly drawn to a method of producing fructan in a plant comprising constructing at least one recombinant DNA molecule comprising an embryo specific promoter operably linked to at least "a portion" of at least one coding sequence for a fructosyltransferase, operably linked to a vacuole targeting sequence.

In contrast, the specification only provides guidance for Jerusalem artichoke SST (contained within SEQ ID NO:1), Jerusalem artichoke FFT (contained within SEQ ID NO: 2), Guayule SST (SEQ ID NO:10) and Guayule FFT (SEQ ID NO: 13) coding sequences. The specification does not provide guidance for coding sequences from any other plant source, or any other organismal source in which a fructan with a degree of polymerization of 3 is produced in the embryo of a plant.

The Federal Circuit has recently clarified the application of the written description requirement. The court stated that a written description of an invention "requires a precise definition, such as by structure, formula, [or] chemical name, of the claimed

subject matter sufficient to distinguish it from other materials." University of California v. Eli Lilly and Co., 119 F.3d 1559, 1568; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The court also concluded that "naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material." Id. Further, the court held that to adequately describe a claimed genus, Patent Owner must describe a representative number of the species of the claimed genus, and that one of skill in the art should be able to "visualize or recognize the identity of the members of the genus." Id.

Finally, the court held:

A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus. Id.

See also MPEP section 2163, page 174 of chapter 2100 of the August 2005 version, column 1, bottom paragraph, where it is taught that

[T]he claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence.

See also Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., 18 USPQ 2d 1016 at 1021, (Fed. Cir. 1991) where it is taught that a gene is not reduced to practice until the inventor can define it by "its physical or chemical properties".

Given the claim breadth and lack of guidance as discussed above, the specification fails to provide an adequate written description of the genus of sequences as broadly claimed. Given the lack of written description of the claimed genus of sequences, any method of using them, such as transforming plant cells and plants therewith, and the resultant products including the claimed transformed plant cells and plants containing the genus of sequences, would also be inadequately described. Accordingly, one skilled in the art would not have recognized Applicant to have been in possession of the claimed invention at the time of filing. See the Written Description Requirement guidelines published in Federal Register/ Vol. 66, No. 4/ Friday January 5, 2001/ Notices: pp. 1099-1111.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 3 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim states "wherein said fructosyltransferase is selected from" indicating a single fructosyltransferase enzyme is being claimed, however, the Markush group states "from the group consisting of sucrose:sucrose fructosyltransferase and the combination of sucrose:sucrose fructosyltransferase and fructose:fructose fructosyltransferase". It is unclear to the Examiner whether "the combination of sucrose:sucrose fructosyltransferase and fructose:fructose fructosyltransferase" is referring to a chimeric gene that contains portions of each gene but encodes a single

enzyme, or whether the statement is referring to a construct that actually contains two fructosyltransferase genes and therefore encodes two enzymes as opposed to one. If the claim is intended for the latter, the claim should be reworded so that the fructosyltransferase is not stated only in the singular. If the claim is intended to mean the former, it is suggested that claim be reworded to precisely point out the claimed invention. New matter should be avoided.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 23 and 24 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claims are broadly drawn to grain from a transgenic plant. However due to Mendelian inheritance of the transgene, some seeds produced by a transgenic plant will not have a copy of the transgene, and will thus be indistinguishable from naturally occurring seeds. Accordingly, the claims are drawn to a product of nature, which is non-statutory subject matter.

See Diamond v. Chakrabarty, 447 U.S. 303 (1980), Funk Bros. Seed Co. V. Kalo inoculant Co., 233 U.S. 127 (1948), and American Fruit Growers v. Brogdex Co., 283 U.S. 2 (1931).

This rejection can be overcome by amendment of claims 23 and 24 to indicate that the grain comprises the recombinant DNA molecule.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-5, 7-11, 13-17 and 23-24 are rejected under 35 U.S.C. 102(e) as being anticipated by Caimi (US Patent 6365800 filed on 02/05/1999) in light of Koops et al (US Patent 6664444 filed on 10/16/2000).

Claims 1-2, 4-5, 7, 13-14, and 23-24 are drawn to at least one recombinant DNA molecule and a plant comprising said recombinant DNA molecule(s) wherein said DNA molecule comprises an embryo specific promoter operably linked at least a portion of at least one coding sequence for a plant fructosyltransferase, operably linked to a vacuole targeting sequence, said molecule sufficient to express a protein capable of producing fructan having a degree of polymerization of at least three in an embryo of said plant, wherein said fructan is inulin, and wherein said plant is a cereal, wherein the cereal is corn, and wherein the fructosyltransferase coding sequence is selected from a dicot or a monocot. The claims are further drawn to grain of said plant.

Claims 3, 8-11, and 15 are drawn to a plant comprising the recombinant molecule(s) described above wherein at least one fructosyltransferase comprises

sucrose:sucrose fructosyltransferase. The claims are further drawn to the recombinant molecule wherein the molecule(s) comprise two fructosyltransferases wherein the first fructosyltransferase comprises sucrose:sucrose fructosyltransferase and the second fructosyltransferase comprises fructan:fructan fructosyltransferase, and more specifically, a plant comprising a first DNA molecule comprising sucrose:sucrose fructosyltransferase and a second DNA molecule comprising fructose:fructose fructosyltransferase.

Claims 16 and 17 are drawn to a method of producing fructan in a plant comprising constructing at least one recombinant DNA molecule comprising an embryo specific promoter operably linked to a vacuole targeting sequence operably linked to at least a portion of at least one coding sequence for a fructosyltransferase, transforming a plant cell with said construct, regenerating said plant to produce seed, harvesting seed from said plant and extracting fructan from said seed wherein the fructan is inulin.

Caimi teaches a maize plant transformed with a recombinant DNA molecule comprising an embryo specific promoter, a vacuole targeting sequence, a Jerusalem artichoke FFT gene, and a maize plant transformed with a recombinant DNA molecule comprising an embryo specific promoter, a vacuole targeting sequence, a Jerusalem artichoke SST, and a maize plant comprising both heterologous genes, wherein a polyfructan with a degree of polymerization of at least three is produced (see column 8, lines 28-33, column 9 second and third full paragraphs, column 11 lines 25-30, column 12 last paragraph, column 13 first paragraph and lines 33-35, column 14 second

paragraph, column 14 last paragraph, column 15, column 16, and claims 1,2, 4-8, for example).

Caimi also teaches a method for increasing the level of fructans comprising the construction of recombinant DNA molecule comprising an embryo specific promoter operably linked to a vacuole targeting sequence operably linked to a Jerusalem artichoke SST gene, the transformation of a maize plant with said molecule, regeneration of said plant, and the extraction of fructans from the seeds of said transgenic plant (see column 8, lines 28-33, column 9 second and third full paragraphs, column 11 lines 25-30, column 12 last paragraph, column 13 first paragraph, and lines 33-35, column 14 second paragraph, column 14 last paragraph, column 15, column 16, and claims 1,2, 4-8, for example).

Caimi does not teach the term "inulin" when disclosing the polyfructans that are produced from the transgenic maize plants, however, in light of Koops et al (US Patent 6664444), where Koops et al teach that inulin is produced from Jerusalem artichoke SST and FFT genes (see column 6 lines 23-29, and column 7 third paragraph, for example), it is evident that inulin is inherently produced from the transgenic plant taught by Caimi.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-11, 13-17 and 23-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Koops et al (US Patent 6664444 filed on 10/16/2000) in view of Caimi et al (US Patent 6365800 filed on 02/05/1999).

Claims 1-2, 4-7, 13-14, and 23-24 are drawn to at least one recombinant DNA molecule and a plant comprising said recombinant DNA molecule(s) wherein said DNA molecule comprises an embryo specific promoter operably linked at least a portion of at least one coding sequence for a plant fructosyltransferase, operably linked to a vacuole targeting sequence, said molecule sufficient to express a protein capable of producing fructan having a degree of polymerization of at least three in an embryo of said plant, wherein said fructan is inulin, and wherein said plant is a cereal, wherein the cereal is corn, and wherein the fructosyltransferase coding sequence is selected from a dicot or a monocot. The claims are further drawn to grain of said plant. Claim 6 is drawn to the plant described above wherein the plant is soybean.

Claims 3, 8-11, and 15 are drawn to a plant comprising the recombinant molecule(s) described above wherein at least one fructosyltransferase comprises sucrose:sucrose fructosyltransferase. The claims are further drawn to the recombinant molecule wherein the molecule(s) comprise two fructosyltransferases wherein the first fructosyltransferase comprises sucrose:sucrose fructosyltransferase and the second fructosyltransferase comprises fructan:fructan fructosyltransferase, and more specifically, a plant comprising a first DNA molecule comprising sucrose:sucrose

fructosyltransferase and a second DNA molecule comprising fructose:fructose fructosyltransferase.

Claims 16 and 17 are drawn to a method of producing fructan in a plant comprising constructing at least one recombinant DNA molecule comprising an embryo specific promoter operably linked to a vacuole targeting sequence operably linked to at least a portion of at least one coding sequence for a fructosyltransferase, transforming a plant cell with said construct, regenerating said plant to produce seed, harvesting seed from said plant and extracting fructan from said seed wherein the fructan is inulin.

Koops et al teach a cereal, wherein the cereal is maize, and a soybean plant transformed with a recombinant DNA construct comprising a 1-SST enzyme encoding gene and a 1-FFT enzyme encoding gene wherein the two genes are operably linked to a vacuole targeting sequence, and a method for producing a modified inulin from a plant comprising insertion of the genetic construct described above into the host cell of a plant, and regenerating the plant (see claims 4, 6, 10, 11, 13, 14, 18-21, and 29-33, for example). The production of seed, the harvesting of the seed and extracting the fructan wherein the fructan is inulin are also disclosed (see column 12 lines 46-56, and column 13 lines 30-44, for example).

Koops et al do not teach an embryo specific promoter.

Caimi teaches an embryo specific promoter as stated above.

Given the state of the art, and the disclosures by Koops et al and Caimi it would have been obvious to one of ordinary skill in the art to modify the genetic construct taught by Koops et al by incorporating the embryo specific promoter taught by Caimi et

al, as suggested by Caimi et al (column 9 lines 27-47, for example), to generate production of inulin specific to the embryo.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brent Page whose telephone number is (514)-272-5914. The examiner can normally be reached on Monday-Friday 8-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571)-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Brent T Page

DAVID T. FOX
PRIMARY EXAMINER
GROUP ~~180~~ 1638